

REMARKS

Reconsideration of the application in light of the present amendments and the following remarks is respectfully requested.

I. Status of the Claims:

Claims 1 and 16 and have been amended as discussed below. No new matter has been added by these amendments. Claims 7, 10, 14, 15 and 27 have been canceled without prejudice. Therefore, claims 1, 5, 6, 8, 9, and 16-18 are currently pending and at issue in the application.

(A) Claim Amendments

Claims 7, 10, 14, 15 and 27 have been canceled without prejudice. Claims 1 and 16 have been amended as discussed below.

Claims 1 has been amended to recite a method of assessing risk of Alzheimer's Disease in a subject. Support for the present amendment is found at page 3, lines 1-3, page 6, line 26 to page 7, line 3 and Example 1, page 17. Claims 1 and 16 have also been amended to remove cerebral spinal fluid as a member of the group of biological samples of the presently claimed invention. No new matter has been introduced by the removal of this Markush group member. Claims 1 and 16 have been further amended to clarify the meaning of "normal level". Support for the amendment is found at page 3, lines 12-18. No new matter has been introduced by the current amendment.

II. Claim Rejections:

The Examiner's rejections of the claims are summarized and addressed below.

(A) Rejections under 35 U.S.C § 112, first paragraph

The Examiner has rejected claims 1, 5-10, 14-18 and 27 under 35 U.S.C. §112, first paragraph for lack of enablement. The Examiner contends that while the present specification enables claims directed to a method of assessing the risk of a subject having Alzheimer's Disease, the specification does not enable claims directed to assessing the risk of neurodegenerative disorders associate with amyloidosis other than Alzheimer's Disease.

In response, but without conceding the correctness of the Examiner's rejection, claims 7, 10, 14, 15 and 27 have been canceled. Additionally, claim 1 has been amended to

recite a method of assessing risk of Alzheimer's Disease in a subject. Applicants submit that the present amendment addresses and overcomes the present rejection.

The Examiner has also rejected the above mentioned claims for lack of enablement, contending that the specification does not enable claims directed to determining a level of anti-AB₄₂ antibody in cerebral spinal fluid. Without conceding the correctness of the Examiner's rejection, claims 1 and 16 have been amended to delete cerebral spinal fluid as a member of the group of biological samples from which the level of anti-AB₄₂ antibody may be determined. Applicants submit that the present amendment addresses and overcomes the Examiner's rejection.

The Examiner has further rejected claim 7 for lack of enablement. Again, without conceding the correctness of the Examiner's rejection, claim 7 has been cancelled without prejudice, thereby rendering the present rejection moot.

In view of the foregoing remarks and amendments, applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

(B) Rejections under 35 U.S.C §112, second paragraph

The Examiner has rejected Claims 1, 5-10 and 14-18 as indefinite. Particularly, the Examiner contends that the phrase "normal level determined from the level of anti-AB₄₂ antibody in a biological sample" renders claims 1 and 10 and 16 vague and indefinite.

Without conceding the correctness of the Examiner's rejection, claim 10 has been cancelled without prejudice. Additionally, in response to the Examiner's rejection, and as suggested by the Examiner, claims 1 and 10 have been amended. Specifically, claims 1 and 10 have been amended to further recite the normal level being determined from an average of the level of anti-AB₄₂ antibody in a biological sample from a population consisting of age-matched normal subjects. Applicants submit that the present amendment defines with particularity the subject matter of the presently claimed invention, thereby rendering the claims definite and overcoming the present rejection.

In view of the present amendment and remarks, applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

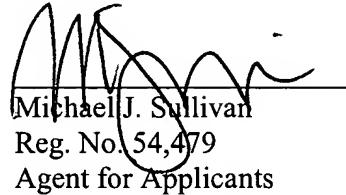
CONCLUSIONS

In view of the above amendments and remarks, the applicants respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

Dated: May 17, 2004



Michael J. Sullivan
Reg. No. 54,479
Agent for Applicants

DARBY & DARBY, P.C.
Post Office Box 5257
New York, NY 10150-5257
Phone (212) 527-7700